REMARKS/ARGUMENTS

This Amendment addresses the issues raised in the Official Action of November 2, 2007, a Final Rejection. Claims 12-14, 17-22, 25-30 and 31-35 remain in the application of which claims 17-22, 25-30 and 33-35 have been withdrawn from consideration as directed to non-elected subject matter. The claims remaining in the case and active are claims 12-14, 31 and 32.

Claims 9-11, 15-16, 23-24 have been, without prejudice or disclaimer, deleted to reduce issues.

Claims 12-14 and 31-32 have been amended.

Response to Claim rejections – 35 USC § 112

Claims 9-11 and 23-24 have been deleted in order to advance examination and remove the enablement rejections.

Claims 12-14, which refer to a method for providing protection from kidney, find basis in from page 7-last two lines to page 9-table 3. These claims are amended to be specific to lithium as the nephrotoxic agent.

Claims 31-32 have been amended for purposes of clarity to remove an unnecessary phrase.

Claims 12-14, 31 and 32 as above amended are fully compliant with 35 USC §112.

Response to Claim rejections – 35 USC § 103

Calvani et al.

This applies, if at all, only to claims 12-14. Newly amended claims 12-14 refer to a method for protecting kidney from dysfunction caused by lithium by administering acetyl L-carnitine in combination with propionyl L-carnitine.

Calvani et al. U.S. 5,955,424 describe the administration of L-carnitine **or** alkanoyl L-carnitine for inhibiting nephrotoxicity due to immunosuppressant drugs. Calvani et al. do not discloses a combination comprising the two compounds in a single formulation and, more importantly Calvani et al. do **not refer to lithium** as a nephrotoxic agent.

The experimental results reported in from page 7 - last 5 lines to page 9 – table 3, of the specification of the subject application, show that the combination of acetyl L-carnitine with propionyl L-carnitine have a **synergic effect**. From the data in table 3 it can be easily understood that the post-lithium-infusion time is **halved** by the combination in comparison to the two components alone.

The results could not be predicted merely by looking at the disclosure of Calvani et al. In fact, the skilled person could not expect the behavior of the combination and the presence of a synergic effect by looking at the effects of the single components.

The evidence of unexpected results as shown by the data provided in Table 3 of the originally filed specification provide sufficient basis for demonstration of a surprising and synergistic effect provided by L-carnitine in combination with propionyl L-carnitine. The results presented in the original specification accompanied by the executed declaration signed by the inventors would have significant evidentiary weight, comparable to the weight given to an executed declaration. It is well established by the Federal Circuit that "the examiner must consider comparative data presented in the specification which is intended to illustrate the claimed invention in reaching a conclusion in regard to the obviousness of claims." *In re Margolis,* 785 F.2d 1029, 228 U.S.P.Q. 1123, 1129 (Fed. Cir. 1993).

Moreover, Calvani et al. do not give any indication on any beneficial effect on nephropathies caused by lithium. Thus, the skilled person could not foresee the effect of the combination on the damage specifically caused by lithium, which is tubular necrosis.

In view of the above, claims 12-14 and 31-32 are inventive over Calvani et al.

Calvani et al. in view of Walker 1982

This rejection pertains, if at all, to claims 12-14, 31 and 32. Walker represents the background art on damage caused by lithium on the kidney. The applicant was aware at the time of filing of the nephrotoxic activity of lithium, as mentioned in page 8 lines 1-2, and knew that lithium causes tubular necrosis. Walker et al. do not add any additional information to those given by Calvani et al.

Calvani et al is discussed above. Moreover, Calvani et al. teach that cyclosporin A causes a general arterial disease which results in tubular atrophy and glomerular atrophy in kidney, as other **vasculotoxic** immunosuppressive drugs.

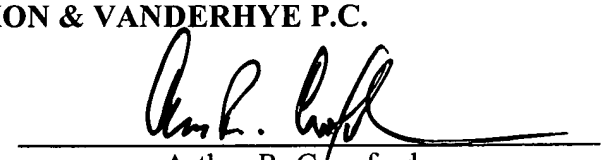
The person skilled in the art knows that, since the kidneys have an elaborate structure and a complicated physiology, the arterial diseases of Calvani et al. are distinct from the tubular necrosis induced by lithium (as disclosed by Walker 1982). Thus, he could not predict, with a reasonable expectation of success, that the combination have a protective effect on damages caused by lithium since the subject of Calvani et al is vasculotoxic immunosuppressive drugs, not lithium.

In view of the above, claims 12-14 and 31-32 are inventive over Calvani et al. in combination with Walker 1982.

Favorable consideration of claims 12-14, 31 and 32 is requested. The examiner is requested to rejoin any or all of the withdrawn claims, as appropriate.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 

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